K072296

THERAGENICS CORPORATION®

SEP 26 2007

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Device Name:	Point of Care Stranding System
Device Model Number:	1004-00
Classification Name:	Radionuclide Brachytherapy Source (KXK)
Device Classification:	Class II
Predicate Devices:	TheraStrand (K040339) CP Spacer (K013964) MICK 200-TPV Applicator (K890341) Bard Sourcelink (K041576)
Manufacturer:	Theragenics Corporation® 5203 Bristol Industrial Way Buford, GA 30518 USA
Establishment Registration Number:	1037598
Official Contact:	Betsy Cortelloni RA/QS Manager Theragenics Corporation® 5203 Bristol Industrial Way Buford, GA 30518 Phone: 770-271-0233

Intended Use: The Point of Care Stranding System provides a method for the physician to custom configure and assemble sterile TheraSeed® strands in the operating room at the time of the implant procedure. The Point of Care System may also be used to custom load sterile I-Seed in non-stranded configurations.

Device Description: The Point of Care Stranding System is designed to facilitate intra-operative treatment planning by providing a means of joining sterile TheraSeed® sources with sterile spacers of varying lengths to form the desired strand configuration. The device also facilitates transfer of the sterile strand either directly into a CP Medical brachytherapy needle, or via a transfer tube into a MICK style applicator needle. The device system consists of the following components: Assembly Device, Seed Magazine, Spacer Cartridges, Stylet, and Transfer Tube (optional).

Substantial Equivalence Comparison: The application (linking process) of the Point of Care Stranding System is substantially equivalent to the Bard Quick-Link (K041576). Both systems use a press-fit concept. The Bard system presses seeds into the end of a bioabsorbable "sleeve" or link (SourceLink) to form the seed array. The Point of Care System presses solid bioabsorbable spacers into the concave endcups of TheraSeed® to link alternating seed-spacer pairs.

Design Verification: Design verification of the Point of Care Stranding System was accomplished through bench testing including validation of manufacturing processes, verification of device and component performance, sterilization and package validations. The testing demonstrated the functional performance of the device in accordance with the design specifications. Additionally, User Validation was conducted to verify that the device could be successfully used to assemble, transfer, and implant the strand while maintaining strand integrity.

Conclusion: The results of verification testing confirmed that design inputs were achieved and the cumulative test results demonstrated the functionality, safety and effectiveness of the Point of Care Stranding System and its components, as well as its substantial equivalence to the predicate device and methodology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 26 2007

Ms. Betsy Cortelloni
RA/QS Manager
Theragenics Corporation
5203 Bristol Industrial Way
BUFORD GA 30518

Re: K072296
Trade/Device Name: Point of Care Stranding System
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: August 16, 2007
Received: August 17, 2007

Dear Ms. Cortelloni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(K) number (if known): K072296

Device Name: Point of Care Stranding System

Indications for Use:

The Point of Care Stranding System provides a method for the physician to custom configure and assemble sterile TheraSeed® strands in the operating room at the time of the implant procedure.
The Point of Care System may also be used to custom load sterile I-Seed in non-stranded configurations.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFRR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072296